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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,459	12/22/1999	MARK D. FIDOCK	PC10315AGPR	7428

7590

07/01/2002

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/01/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/1471,459

Applicant(s)

Fidack

Examiner

DUFFY

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6-6-02.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-6, 8-12, 14, 17, 26-36 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-6, 8-12, 14, 17, 26-36 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Restriction/Election

Sequence Compliance

1. This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 because at least claims 1-3 are not in compliance with the sequence rules. Reference to a Figure of Formulae is not a proper reference to a particular sequence identifier and is not particularly identified by a unique sequence identifier in the claims. Correction is required.
2. A substitute specification comprising the changes to the specification as set forth in the preliminary amendment filed 12-22-99 is required pursuant to 37 CFR 1.125(a).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

It is noted that the substitute specification provided on 12-20-01 did not properly incorporate the preliminary amendment of 12-22-99. The amendment can not be entered into the substitute specification filed on 12-20-01.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 2, 17, 29-31 and 36, drawn to polypeptides/enzymes, classified in class 435, subclass 183.

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- II. Claims 3-6, 8, 9, 16, and 32-35, drawn to nucleic acids encoding enzymes, vectors and host cells, classified in class 536, subclass 23.2.
 - III. Claims 10-12, drawn to methods of screening for agents that alter the activity of the enzyme, classified in class 435, subclass 4.
 - IV. Claims 26-28, drawn to methods of screening for agents that alter the expression of the nucleic acids encoding enzymes, classified in class 435, subclass 6.
4. The inventions are distinct, each from the other because of the following reasons:
- Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein could be used in a method of therapeutics or administered to make an antibody.
5. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids as claimed could be used in a method of making the polypeptide, in a method of detection of expression of the polypeptide or in a therapeutic method.
- Inventions I and II are drawn to separate products that have different chemical structures (amino acids versus nucleotides) and have different functions based on those structures. Further, the nucleic acid is not required to produce the polypeptide inasmuch

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as the polypeptide can be made synthetically or purified from nature. Inventions III and IV are distinct methods that rely upon the use of separate and distinct products. Each of the methods have different goals as evidenced by their preambles, utilize different reagents (amino acids versus nucleic acids) and have different final outcomes. As such, the methods are distinct as claimed.

6. If applicants elect Group I, they must elect from the following species: Claims 1, 2, 17, 29-31 and 36 are generic to a plurality of disclosed patentably distinct species comprising: Z1, Z2, Z3, Z4, Z5, Z6, Z7, Z8, Z9, Z10, Z11, Z12, Z13, Z14, Z15, Z16, Z17, Z18, Z19, Z20, Z22, Z23, Z24, Z25, Z26 of Formulae I, SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

7. If applicants elect Group II, they must elect from the following species: Claims 3-6, 8, 9, 16, and 32-35 are generic to a plurality of disclosed patentably distinct species comprising: Z1, Z2, Z3, Z4, Z5, Z6, Z7, Z8, Z9, Z10, Z11, Z12, Z13, Z14, Z15, Z16, Z17, Z18, Z19, Z20, Z22, Z23, Z24, Z25, Z26 of Formulae I, SEQ ID NO:2, SEQ ID NO:4, and SEQ ID NO:6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. A complete response to this Office action requires (a) proper sequence compliance for the claims; (b) a substitute specification and © an election and a species election.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

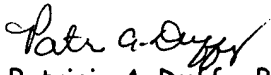
Patricia A. Duffy, Ph.D.

June 29, 2002

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Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600